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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room. 1061  
Rockville, Maryland 20852

**Subject: Comment to the FR Notice of June 28, 2000: Guidance for Industry:  
Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for  
Treatment (Docket No. 00D-1318)**

To Whom It May Concern:

Novartis Pharmaceuticals Corporation has reviewed the above Federal Register Notice and requests the following clarification.

Under section II.B.2, "Claims related to Improved Wound Healing - Accelerated Wound Closure", we request clarification with regard to the statement that a claim of *improved incidence of closure* suffices to explain the clinical benefit and should not be supplemented by an additional claim of *accelerated wound closure*.

Please clarify whether *accelerated wound closure* refers to the rate of wound closure per unit time or to the time to complete closure, as it is unclear under which of these circumstances an additional claim could be made.

Thank you for the opportunity to comment.

Sincerely,

Ann Shea

00D-1318

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